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CPSC-IAG-00-1157
Modification No. 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
INTER/INTRA-AGENCY AGREEMENT (IAA)
Payable Agreements (CDC is Procuring Agency)

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

6016 8/22/02

1. CDC IAA #: (10 to 13 digits)	2. PARTICIPATING AGENCY IAA #:	3. TYPE OF AGREEMENT
00FED05404-06	CPSC-IAG-00-1157	☐ New ☑ Modification ☐ Administrative Modification Number: 6

4. TITLE OF PROJECT:
Adverse Effects Due to Therapeutic Drugs

5. DESCRIPTION OF WORK: *(Please attach)*	6. AMOUNT: *(Not to exceed without written modification)*
See Attachment	$ 51,250.00

7. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY:	LIAISON NAME:	PHONE #:
Consumer Product Safety Commission 4330 East West Highway, Rm 517 Bethesda, MD 20814-4408	Art McDonald	(301) 504-0539
	EMAIL ADDRESS: amcdonal@cpsc.gov	FAX #: (301) 504-0038

8. NAME AND ADDRESS OF CDC, CENTER, INSTITUTE OR OFFICE:	LIAISON NAME:	PHONE #:
National Center for Injury Prevention and Control Division of Injury and Disability Outcomes and Programs 4770 Buford Highway, NE, Mailstop F-41 Atlanta, GA 30341	Dan Budnitz, M.D.	(770) 488-1486
	EMAIL ADDRESS: DBudnitz@cdc.gov	FAX #: (770) 488-4338

9. PROJECT PERIOD:		FUNDING PERIOD:	
from: 07/22/2002	through: 12/31/2002	from: 07/22/2002	through: 09/30/2002

10. CDC AUTHORITY:
☑ Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535 and 1536 (See also item #14)
☐ Other *(Please specify)* _____

11. PARTICIPATING AGENCY AUTHORITY:
Section 601 of the Economy Act, as amended (31 U.S.C. 1535) and the Consumer Product Safety Act.

12. CDC FUNDING INFORMATION: FOR CDC USE ONLY *(CDC internal form 6012 - modified Document History Record)* APPROPRIATION NUMBER: 7520943

T.C. (For Accounting Use Only)	FY (2 digits) (Required)	DOC. REF. (For Accounting Use Only)	DOC. NO. (Original 10 digits) (Required)	CAN (7 digits) (Required)	O.C. (4 digits) (Required)	ALLOWANCE (5 digits) (For Budget Use Only)	$ AMOUNT
050	02	214	00FED05404	29213353	25.38	2-1X717	$51,250.00
		214					
		214					
		214					
		214					
		214					
		214					
		214					

6012 ADMINISTRATIVE APPROVAL NAME and EMAIL ADDRESS: *(Please print)*
Diana Miles
Administrative Officer, DIDOP, NCIPC
dzm6@cdc.gov
(Should not be the same as Block #18)

FMO BUDGET ANALYST SIGNATURE:

ADMINISTRATIVE APPROVAL SIGNATURE: Diana Miles 7/22/02

CDC 0. 1270 (E), CDC IAA Short Form #21, Rev. 5/2000, CDC Adobe Acrobat 4.0 Electronic Version, 2/2001

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention

INTER/INTRA-AGENCY AGREEMENT (IAA)

Payable Agreements (CDC is Procuring Agency)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC IAA #: 00FED05404-06

13. ADMINISTRATIVE BILLING REQUIREMENTS: CDC's ALC is 75090421. Other Agency's ALC: *(required)* 61000001

Billing is to be made through the use of the Online Payment and Collection (OPAC) system. **Please include CDC's Official IAA # from Block #1 on all OPAC billings and correspondence.** When CDC provides funds to the performing agency, in advance of receiving the goods or services, the performing agency agrees to provide,within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. The statements shall be provided to the following address: **DHHS, CDC, FMO, AP, Attn: ADVANCES/OPAC Desk, MS D-06, 1600 Clifton Road, Atlanta, GA 30333.** (If required by other agency, CDC's Tax Identification # is 586051157.)

14. ADDITIONAL BILLING REQUIREMENTS: ***(This block must be completed if procuring services under the Economy Act.)***

☑ All funds provided by CDC under this agreement must be obligated by the performing agency by the end of the FY in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. The CDC Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 15 days before the end of the FY so that the agreement may be modified to reduce the funding amount when appropriate. This notification shall be provided to the following address:

DHHS, CDC, FMO, AP, Attn: OPAC Desk, MS D-06, 1600 Clifton Road, Atlanta, GA 30333.

15. PARTICIPATING AGENCY FUNDING and/or INFORMATION:

(Please include name, telephone number, and email address of contact person.)

Name:	Telephone #:	Email:
Linda. Murr	(301) 504-0029, x2239	lmurr@cpsc.gov

16. ☐ The participating agency as a signatory to the Common Rule states that in accepting these Interagency Agreement funds, it will abide by the human subjects research requirements stated in the Common Rule, and certify that all necessary assurances and institutional review board (IRB) approvals are obtained.

☐ The participating agency is NOT a signatory to the Common Rule. Upon issuance of these Interagency Agreement funds, it is the responsibility of the CDC Center, Institute, or Office (CIO) to certify that all necessary assurances and institutional review board (IRB) approvals are obtained. The CIO Associate Director for Science (ADS) must determine the Applicability of Human Subjects Regulations.

17. OTHER REQUIREMENTS:

A. Travel under this agreement is subject to allowances authorized in accordance with Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.

B. CDC will retain the title to any equipment procured under this agreement, unless otherwise justified in the statement of work.

18. *CDC ACCEPTANCE: (please print)*

Name: Sue Binder, M.D.

Title: Director, NCIPC, CDC

Email address: SBinder@cdc.gov

Signature: Debra A Matt Date: 8/13/02

19. *PARTICIPATING AGENCY ACCEPTANCE: (please print)*

Name: Donna Hutton

Title: Contracting Officer, US Consumer Product Safety Commission

Email address: dhutton@cpsc.gov

Signature: Donna Hutton Date: 8/6/02

This agreement may be terminated by either agency upon a 30-day advance written notice. This agreement may be modified by mutual written consent of all parties.

CDC 0.1270 (E), CDC IAA Short Form #21, Rev. 5/2000, CDC Adobe Acrobat 4.0 Electronic Version, 2/2001

INTERAGENCY AGREEMENT BETWEEN THE CONSUMER PRODUCT SAFETY COMMISSION (CPSC) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) (00FED05404-06)

This document sets forth the terms of agreement for services, supplies, and/or material between the U.S. Consumer Product Safety Commission (CPSC) and the Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC).

This document serves as an addendum to the Interagency Agreement (number 00FED05404) between the Centers for Disease Control and Prevention and the U.S. Consumer Product Safety Commission covering the expansion of the National Electronic Injury Surveillance System (NEISS) to collect data on all injuries. This addendum covers a special study entitled: "**Adverse Events due to Therapeutic Drugs (ADE)**" which is outlined below. Additional study forms and documentation are attached as Appendixes A-B.

I. DESCRIPTION OF SERVICES

A. Background

Adverse events due to therapeutic drugs (ADEs) may be responsible for over 100,000 deaths a year, which would make ADEs the 5th leading cause of death in the United States (JAMA 1998;279:1200-5, 1216-7). Several large studies have focused on ADEs in the hospital setting. In the outpatient setting, however, we know relatively little about adverse drug events.

The National Electronic Injury Surveillance System – All Injury Program (NEISS) can play an important role in collecting information about outpatient ADEs. However, according to a recent audit, NEISS coders were less successful in identifying ADEs than any other cause of injury. According to this audit, only 26.5% of ADEs were correctly identified.

In the Pre-Pilot phase of this project, a training module for improving the case finding and case reporting ADEs was developed and pilot tested in four NEISS hospitals. CPSC has actively promoted the pre-pilot to NEISS hospitals and provided timely data to NCIPC. The NEISS coders have been receptive to the training and have helped improve the training module.

Preliminary data from the first of these hospitals shows that this hospital has more than doubled the number of cases of ADEs reported.

B. Purpose

The pilot study will now be expanded to include all 10 hospitals (rather than only 5) in the collection of specific additional data on the ADE cases identified using a one-page form. The termination date for data collection using the one-page form will also be extended to the end of the current fiscal year (rather than from 60 days after to supplemental training). Lastly, the computer programming to incoporate the paper form into NEISS-AIP as a "second screen" will be completed so that reporting of ADEs may be expanded in the future.

C. Overview of Methods

As the pre-pilot study demonstrated feasibility of training NEISS hospital coders to identify ADEs, the pilot study will now assess the ability of NEISS to collect additional specific data on ADEs using a paper or electronic one-page form. For each form completed, the hospital coordinators will be paid according to CPSC contract.

Effectiveness of the training will be evaluated by comparison of pre- and post-intervention counts of cases of ADEs in individual pilot study hospitals and comparison of pre- and post-intervention counts of cases of ADEs between pilot study hospitals and non-participating hospitals. The data from the paper form will also be entered into an electronic database for detailed analysis.

Finally, groundwork for future electronic reporting of the more specific information outlined in the one-page form will begin by developing the computer programming necessary to convert the paper form to an electronic "second screen" integrated into NEISS-AIP. This model of creating "second screens" has been used successfully in many other NCPIC collaborative efforts.

D. Pilot Study

1. Sample of hospitals: CPSC will recruit 10 hospitals, ideally 2 from each hospital strata to participate in the pilot study.

B. Supplemental Training: All 10 hospitals will receive supplemental training based on a training manual refined during the Pre-pilot (Appendix A). In addition, the hospital coordinators from all these 10 hospitals will receive training on reporting specific information on the ADE cases using a paper or electronic one-page form developed by NCIPC and CPSC. The NCIPC researcher and CPSC laisons will be available to hospital coordinators for questions for questions during the study period.

C. Data Collection Form: The additional one-page data collection forms (Appendix B) will be given to the hospital coordinators at the time of supplemental training. From the day after the supplemental training until the end of the fiscal year 2002, the hospital coordinators will complete the one-page forms for all ADE cases and return them to CPSC by the dates specified on the forms. If agreed to by the hospital coordinator, CPSC, and the NCIPC researcher, this data collection may be completed by electronic means. CPSC will coordinate payment for data colletion and will manage the collection and data quality and completeness of these forms.

D. Post-intervention feedback: At certain intervals (approximately 1, 3, and 6 weeks after the supplemental training) the NCIPC researcher or the CPSC hospital laison will contact the NEISS hospital coordinators from the hospitals in the pilot study for questions, problems, or feedback on improving ADE case ascertainment and reporting. If the hospital coordinator chooses to collect information on one-page form electronically, data will be collected and provided to the NCIPC researcher approximately weekly. For those hospital coordinators choosing to use the paper one-page form, a dataset of approximately 4 weeks of data will be assembled for a preliminary analysis.

E. Evaluation of Effectiveness: For each hospital preliminary data will be requested from CPSC, This dataset will include all cases with product codes indicating involvement of a medication from 60 days preceding the supplemental training to the end of the current fiscal year. These cases will be reviewed by the NCIPC researcher and the number and type of ADEs collected before and after the supplemental training will be calculated.

The data collected from the one-page forms will also be compiled in an electronic database and linked to the other NEISS data elements for this case. The data on the one-page forms will be compared to the data collected in the narrative comments to determine if the one-page forms provide additional case detail. These data will be made available to the CPSC researcher for detailed analysis.

E. Programming an Electronic Form

The groundwork for future electronic reporting of the more specific information outlined in the one-page form will begin by developing the computer programming necessary to convert the paper form to an electronic form. This electronic form will be integrated in the NEISS computer reporting system used by the hospital coordinators for data entry and by CPSC for quality control. The final verision of the on-page form will be determined by feedback from the pilot study and will be submitted to CPSC for programing no later than September 1, 2002.

II. DURATION OF AGREEMENT

This agreement is approved from the date of signature for both agencies through December 31, 2002.

III. ESTIMATED COSTS

The estimated cost of this pilot study phase of the NEISS Special Study of Adverse Drug Events is **$51,250**. The breakdown in cost is as follows:

CPSC Charges

1. Increasing the number of hospitals completing ADE paper form (5 hospitals x $2500 each)	$12,500
2. Payment for additional cases reported by 5 original hospitals (5 hospitals x $750 each)	$3,750
3. Data entry from paper forms to Access database (10 hospitals x $500 each)	$5,000
4. Programming of electronic version of paper form	$30,000
TOTAL	**$51,250**

IV. FUNDING

All funds provided by CDC in this agreement must be obligated by the performing agency by the end of the fiscal year in which the funds expire. Any unobligated but expired funds may not be used to fund services in subsequent periods. The CDC Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 15 days before the end of the fiscal year so that the agreement can be amended to reduce the obligated amount when appropriate. The notification must be provided to the address cited below (in paragraph V).

V. ACCOUNTING AND BILLING INFORMATION

Funds for this project for FY2002 in the amount not to exceed $51,250 will be transferred to CPSC via OPAC using the following account data:

	From	To
Agency	CDC	CPSC
Agency Symbol	75-09-0421	61-00-0001
Appropriation	7520943	02 PS EXOB 4310 11179 252E
CAN	2921 3353	
Object Class	25.38	
Amount	$51,250	$51,250
EIN No	58-6051157	52-0978750

When billing CDC through the OPAC system, CPSC will reference agreement number: 00FED05404-06.

When funds are provided to the performing agency in advance of services being performed or goods being delivered, the performing agency is required to provide, within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. These statements are also provided to the address below:

CDC, FMO
Attn: OPAC Desk
1600 Clifton Road, MS D-06
Atlanta, FA 30333

VI. EQUIPMENT

There is no equipment to be covered under this agreement.

VII. TRAVEL

No travel costs are associated with this Interagency Agreement.

VIII. CONFLICT WITH EXISTING AGREEMENTS

There is no duplication or conflict with existing agreements, policy or statute.

IX. PROGRAM CONTACTS

CDC: Dan Budnitz, Ph.D.
DIDOP/NCIPC, MS-F-41
4770 Buford Highway, NE
Atlanta, GA 30341-3724
(770) 488-1486

CPSC: Arthur McDonald
4330 East-West Highway
Suite 604D
Bethesda, MD 20814-4408
(301) 504-0539, Ext. 1249

X. BUDGET CONTACTS

CDC: Diana Miles
DIDOP/NCIPC, MS F41
4770 Buford Highway, NE
Atlanta, GA 30341-3724
770/488-1480

CPSC: Deborah P. Hodge
Dir., Div. of Financial Services
4330 East West Highway, Rm 522A
Bethesda, MD 20814-4408
(301) 504-0018, Ext. 1132

XI. MODIFICATION AND CANCELLATION

This agreement may be modified by mutual consent of both parties or canceled upon with 60 days advance written notice by either party.

XII. AUTHORITY

This agreement is entered into under Section 601 of the Economy Act, as amended (31 U.S.C. 1535) and the Consumer Product Safety Act.

XIII. APPROVALS

For NCIPC:

Sue Binder, M.D.
Assistant Surgeon General
Director, National Center for Injury
Prevention and Control

Date: 8/13/02

For CPSC:

Donna Hutton
Contracting Officer
U.S. Consumer Product Safety
Commission

Date: 8/6/02

Appendix A.

TRAINING MANUAL

Tips for Finding Adverse Drug Events (ADEs)

Questions?

Contact:
Dan Budnitz, MD, MPH
770-488-1486 (tel)
770-488-4338 (fax)
dbudnitz@cdc.gov

Table of Contents

I. The Importance of Identifying Adverse Drug Events

When a patient is injured from an allergic reaction to a drug, a severe side-effect of a drug, or by taking a drug in the wrong way, they have had an Adverse Drug Event (ADE).

ADEs can be minor or very serious. In fact, some studies show that ADEs are responsible for over 100,000 deaths a year. However, we know very little about ADEs that happen outside the hospital and cause injuries that are treated in Emergency Departments. With more information about these ADEs, we hope to learn how to prevent many of them, helping thousands of Americans each year.

NEISS hospital coordinators play a crucial role in collecting important information on ADEs. Detecting cases of ADEs can be more difficult than finding the typical injury cases reported in NEISS, however. This supplemental training module has been designed to make finding and reporting cases of ADEs faster and easier.

II. Finding Adverse Drug Events – Three Simple Tips

Detecting cases of ADEs is different than finding typical injury cases because the adverse effects of drugs often look like the symptoms of other injuries or illnesses. However, using the following 3 tips, you will be able to find almost all ADEs

The Three Tips

1. **Review every entry in the *Diagnosis / Impression / Discharge Instruction* sections of the chart**
2. **Look for *Key Words* that link a drug to an injury**
3. **Look carefully at *Certain Symptoms* which may be linked to drugs**

1. Review Every Entry in the Diagnosis / Impression and Discharge Instruction sections of the chart

Often you cannot tell if an injury is due to an ADE by looking at the Emergency Department (ED) log or only the primary diagnosis.

Review all the Diagnoses / Impressions

Review the Discharge Instructions to see if a patient was told to stop a drug

Example: "59 yo F with sick stomach x 3 wks, decreased appetite, occasional chest pain. Dx: Digoxin toxicity"

Explanation: If we look only at the ED log or the chief complaint of "sick stomach," we would miss this ADE. By checking the diagnosis section (Dx), we find that the "sick stomach" was an adverse effect of a drug the patient was taking, Digoxin.

Example: "60 yo F w/ 3 days of numerous bloody bowel movements. Feels weak. Dx: GI bleed; likely upper; probably related to NSAID use"

Explanation: If we look only at the first part of the diagnosis section, we would see only "GI bleed." By checking every entry in the diagnosis section, we find that the

"GI bleed" was probably an adverse effect of a drug the patient was taking, in this case a NSAID.

Example: ED Log: Runny Nose Dx: Bronchitis
Discharge Instruction: Stop Zithromax, take Benadryl and follow-up with primary care doctor

Explanation: If we look only at the log or the diagnosis section, we would miss the ADE. The plan to stop a medication in the discharge instructions gives a clue to an ADE, which was then confirmed in the nursing notes.

2. Look for ***Key Words*** that link a drug to an injury (Look for the abbreviations, too)

Many ADEs can be easily identified by looking for the following key words linked to a medication:

Adverse Reaction (Adv Rxn)

Allergic Reaction (All Rxn)

Anaphylactic Reaction (Anaphylaxis)

Reaction (Rxn)

Side-Effect (S/E, s/e)

Toxicity (tox, excess, overdose, OD)

Secondary to (2nd to, due to, related to, induced by)

Sensitivity to (hypersensitivity to)

Accidentally took

Example: "Patient had reaction to meds"

Explanation: Some charts have very little documentation, but the key word reaction is associated with a drug (in this case the specific medication is missing) so this entry should be collected.

Example: "86 F here yesterday w/seizures. Has redness all over, agitated. Dx. Acute allergic rxn to Dilantin; acute agitation"

Explanation: Again, if we look only at the chief complaint of "redness all over" we would miss the ADE. The diagnosis section tells us that the cause of the redness was an allergic reaction to a drug, Dilantin.

Example: "10 month old male with several bouts of emesis today. Finished taking amoxicillin. Now taking erythromycin for ear infection. Dx: emesis – prob 2nd to erythromycin"

Explanation: This patient has a symptom secondary to a drug, (erythromycin).

Example: "47 yo F w/ side effect to St Johh's Wort. Has lightheadedness and drugged feeling"

Explanation: The patient has a side-effect of a drug, St. John's Wort.

3. Look carefully at *Certain Symptoms* which may be linked to drugs

The following symptoms are typical of ADEs. If you see one of these symptoms, look carefully to see if a medication causes the symptom.

Bleeding (epistaxis)

Rash (hives, urticaria)

Nausea, Vomiting, Diarrhea (N&V, emesis)

Palpatations, Dizzy, Lightheaded (palps, LH)

Example: "51 y/o BF w/ bloody stool in pt w/ IBD on coumadin. Lower GI bleed vs IBD. Dr states that patient should not be on coumadin."

Explanation: The patient has a symptom (bleeding) likely related to the effect of a drug - coumadin.

Example: "16 mo M developed diarrhea after 1 day PO amoxicillin. Dx: antibiotic induced diarrhea."

Explanation: This patient has a symptom (diarrhea) likely related to the effect of a drug - amoxicillin.

III. Reporting Adverse Drug Events

1. When should I report a case that looks like an ADE?

Report *all cases* where a patient sustained an *injury* that is *linked to a drug*

Recall that an injury is: "A medical condition resulting from contact with external forces or energy." Forces can be mechanical, chemical, thermal, electric, or radioactive. Drugs usually cause harmful medical conditions by chemical energy.

Example: "Rash on back and chest after taking amoxicillin"

Example: "Abdominal pain, nausea and vomiting secondary to taking erythromycin"

Example: "Lower GI bleeding attributed to a high INR in a patient taking coumadin"

Drugs are not just prescription medications, they include:

Prescription medications (antibiotics, anti-depressants, narcotics)

Over-the-counter medications (pain-relievers, cold medications, antacids)

Topical medications (creams, ointments)

Other medications (vaccinations, vitamins)

Nutritional supplements (Creatine, St. John's Wort)

Substances taken for "recreational use" (narcotics, stimulants)

Example: "Allergic reaction to Neosporin used on burn to hand"

Example: "Child ingested 10-20 children's vitamins with iron. Dx: iron overdose"

Example: "Male found at local party with decreased level of consciousness, +EtOH, marijuana, and Lortab"

2. When should I NOT report a case which has a drug mentioned?

If the only drug(s) mentioned are illegal (street) drugs such as "crack", "pot", "speed", "ecstasy", do NOT report.*

If the drug listed is *not related* to the reason the patient came to the emergency department, do NOT report.

If the drug causing the injury was given *during the visit* to the emergency department, do NOT report.

The drug listed was used to *treat* an injury, do NOT report.

Example: "Patient had swelling of face after bee-sting. Patient took EpiPen before arriving to hospital."

Explanation: The injury (swelling) was due to the bee-sting. The drug (EpiPen) was used to treat the injury.

* If only illegal (street) drug(s) are mentioned, this case is NOT considered an ADE, BUT the case may very well be in the scope of NEISS, and still should be reported in the typical way as before.

IV. Narrative Comments for Adverse Drug Events

What information should go in the narrative of an ADE

Include as much detail as possible about the drug, circumstances, injury, and treatment

After an injury case attributed to a drug is reported to CPSC, coders at CPSC determine if the injury is an ADE or a poisoning. To make this distinction, the CPSC coders consider drug type, dosage, delivery mechanism, intent, type of injury, and other factors. Therefore, it is important to record as much information as possible about the circumstances of the injury in the narrative comments.

If any of the following information is available, record:

Name of drug (the most specific name reported)

Dosage of drug (number of pills taken, time period in which taken, milligrams in each tablet)

How delivered (swallowed ointment, pill stuck in throat)

Intent of patient (drug taken in suicide attempt, taking another person's drug, child accidentally took)

Injury type (swelling of a body part, rash over a body part, blood per rectum)

Lab tests, if available (INR/PT, digoxin level, phenytoin level)

Treatment (activated charcoal, observation, gastric lavage)

IV. FAQs (Frequently Asked Questions)

What if the ED clinician writes that an event or symptom is "probably" related to a drug?

DO report the event if the clinician uses the following words (or abbreviations) to describe the cause:

- Probable (prob.)
- Likely

Do NOT report the event if these words (or abbreviations)are used to describe the cause:

- Doubt
- Unlikely (not likely)

If you are uncertain, DO report the case and record the exact wording used in the medical record in the narrative comments

What if it is not known if a patient, for example a child, actually took the drug or not?

If the patient was treated for a drug reaction or diagnosed with a drug reaction DO report the event. In these cases especially, try to report as much detail as possible about the circumstances in the narrative comments.

What if I am not sure if a word written in the chart is a medication or not?

In addition to bad penmanship, clinicians may also misspell medication names or use non-standard abbreviations. If it the injury might be linked to a drug, report it. As always, record the word exactly as it is spelled in the medical record.

What if the drug's name is not written in the ED chart?

Whenever possible, the drug name should be included in the narrative that is entered. If no specific drug is mentioned, still enter as much detail as possible in the narrative.

What if an illegal (street) drug, like "crack" or "ecstasy", causes an adverse event?

These events are not considered ADEs; however, these cases may very well be in the scope of NEISS-AIP and should be reported as before.

What if an over-the-counter medication causes an adverse event?

All medications, including overt-the-counter medications can cause ADEs and should be reported. Also report vitamins, nutritional supplements, diet aids, and herbs that cause adverse events.

What if a patient takes a medication in greater dosage than prescribed?

All these cases should be recorded. At CPSC these may be classified as poisonings or ADEs depending on the additional information collected in the narrative.

What if a drug given in the emergency department causes an ADE?

If a patient has an adverse event related to a drug given while the patient is receiving emergency care in the ED, you should NOT report this event. NEISS-AIP is designed to detect injuries that occur before the patient come to the ED

What if a patient was told to stop a drug in the discharge instructions, but there is not other evidence of an ADE?

Patients are told to stop taking drugs for reasons other than ADEs. Therefore, if there is no other evidence for an ADE in the chart, do NOT report this event

What if I have a question about reporting a case?

During this study please feel free to call, email or fax Dr. Dan Budnitz in the National Center for Injury Prevention and Control, CDC. His contact information is on the front cover.

Appendix B.

ADE Study - 1 Page Paper Form

Hospital Name: Case ID#: Patient Age:

Coders Initials: Treatement Date:

1. Where in the medical record did it indicate the presence of an adverse event related to a drug? Circle all that apply.

   Logbook Chief Complaint Section Physician
   Diagnosis/Impression/Assessment

   Nurses Notes Physician Notes Discharge Instructions

2. List the following information about the suspected drugs (up to 2 drugs can be listed)

	Drug #1	Drug #2
What was the name of the drug?		
How much was taken at a time? If a pill, list milligrams (mg) and number of pills	mg # pills	mg # pills
How often did the patient take the drug? (How many times a day)		
How did the patient take the drug? (Orally, Inhaled, Intravenous, Skin contact, Eye contact, or Rectally)		
How long has the patient been taking the drug?		

3. What other drugs was the patient taking? List the names.

4. If any special lab tests were ordered for the adverse drug event, which ones & what where the results?

5. What treatment was given in the ED?

6. Please record any other information describing the event that was not included in the narrative, or the previous questions:

When should I fill out this paper form?

The Training Manual (page 5) has details about when to report a case. Briefly, include all cases in which the patient has an injury that was linked to a drug. Drugs include **prescription medicine, over-the-counter medicine, vaccines, vitamins, nutritional supplements, and herbs**.

DO include cases if a legal drug (e.g. – morphine, Oxycontin, Tylenol #3) is used for "recreational" purposes.

Do NOT need to include cases in which the only drugs are alcohol or illicit substances (e.g. – crack, pot, heroin).

Specific Instructions for reporting Drug Name, Dose, Frequency, Route, and Duration:

Drug Name:	Report the name exactly as it appears on the medical record
Dose: (How much?)	Report the most specific information available. If milligrams (mg) or other unit record the number and units as they appear on the medical record (e.g.- 50 mg, 25 cc). If the dosage is not recorded in specific units, report as specifically as possible (e.g.- 20 pills, ½ a bottle, unknown number of pills).
Frequency:	Report the most specific information available about how often the drug was taken (e.g.- all at once, once a day, 2x a day, 3x a day, every 8 hours, etc.)
Route:	Report how the drug was taken (e.g.- oral, inhaled, intravenous, skin contact, eye contact, rectal)
Duration	Report how long a period the patient was taking the drug. Report the most specific information available (e.g. – 2 days, 3 weeks, etc.)

What about missing information?

If information that is asked for on the form is missing, you may leave it blank, but do try to find and record all details that appear in the emergency department chart. If the chart says "unknown drug" or "unknown dose", please write "unknown" in the appropriate place on the form.

What should I do with the form when it is complete?

Collect all the forms you have completed in one of the pre-addressed, stamped envelopes. Every 2 weeks, or when you have collected 10 forms, mail the forms in a pre-addressed envelope. Recommended dates the envelopes should be mailed are by: August 2, August 16, August 30, September 13, September 27, October 11

What if I have a question?

During this pilot study please feel free to call, fax or email Dr. Dan Budnitz in the National Center for Injury Prevention and Control, CDC. His contact information is:

770-488-1486 (tel)
770-488-4338 (fax)
dbudnitz@cdc.gov

You may also contact your CPSC analyst to ask questions or to contact Dr. Budnitz.